AFFIRMATIVE DEFENSES

For further answer to Plaintiff's Complaint, Defendants respectfully aver:

FIRST AFFIRMATIVE DEFENSE

Plaintiff's Complaint, or certain counts, fails to state a claim against Defendants upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

If the injuries and damages alleged by Plaintiff in the Complaint were actually sustained, such damages and injuries resulted from a preexisting and/or unrelated medical condition and/or idiosyncratic reaction and not from any act or omission on behalf of Defendants or a defect in Ortho Evra®.

THIRD AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint may have been caused, in whole or in part, by the acts or omissions of others for whose conduct Defendants are not responsible.

FOURTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint were caused, brought about or contributed to by her own comparative fault, and any recovery by Plaintiff must therefore be reduced proportionately or altogether barred.

FIFTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint were the result of an independent, intervening, and/or superseding cause. Any alleged action or alleged omission on the part of Defendants was not the proximate cause of such damages and injuries.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred or reduced by the doctrine of avoidable consequences.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff has failed to obtain jurisdiction over Defendants.

EIGHTH AFFIRMATIVE DEFENSE

The United States Food and Drug Administration ("FDA") approved the labeling for Ortho Evra®, and the marketing and/or distribution of Ortho Evra® conformed with FDA requirements and all other applicable statutes at all times pertinent to the Complaint.

NINTH AFFIRMATIVE DEFENSE

Because the FDA approved Ortho Evra®, Plaintiff's claims that Defendants are strictly liable are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2,4 and 6 and comments thereto.

TENTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint are or may be due to her assumption of the risk of use of Ortho Evra®, if any, thereby barring Plaintiff from recovery.

ELEVENTH AFFIRMATIVE DEFENSE

Adequate and complete warnings and instructions were provided with Ortho Evra®. Ortho Evra® was neither defective nor unreasonably dangerous when used according to label instructions.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of express or implied warranty are barred by Plaintiff's failure to give notice.

THIRTEENTH AFFIRMATIVE DEFENSE

Any express or implied warranties alleged to have been made by Defendants were disclaimed.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred by the absence of privity of contract between Plaintiff and Defendants.

FIFTEENTH AFFIRMATIVE DEFENSE

Defendants are entitled to the benefit of all defenses and presumptions which may arise because the design, manufacture, inspection, packaging, issuing of warnings and instructions or labeling of Ortho Evra® were in conformity with the generally recognized, reasonably available and reliable state of the art and prevailing standards in the industry at the time the product was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the Learned Intermediary Doctrine, or the Informed Intermediary Doctrine and/or the principle of Restatement (Second) of Torts § 388.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with regulating prescription drugs, including Ortho Evra®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims, in whole or in part, are preempted expressly and impliedly by the Supremacy Clause of the Constitution of the United States of America and by applicable federal

NINETEENTH AFFIRMATIVE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to <u>Buckman Co. v. Plaintiff's Legal Comm.</u>, 531 U.S. 341 (2001).

TWENTIETH AFFIRMATIVE DEFENSE

If Defendants are found liable to Plaintiff for any non-economic loss, as defined in Article 16 of the New York Civil Practice Law and Rules, and such liability equals 50% or less of the total liability of all persons liable, and the aggregate liability of such other persons equals or exceeds 50% of the total liability. Defendants' liability, if any, to Plaintiff for a non-economic loss shall not exceed Defendants' equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such non-economic loss.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The awarding of punitive damages and Plaintiff's claims for punitive damages are unconstitutional under the constitutions of the United States and the State of New York. The awarding of punitive damages would be unconstitutional because punitive damages are a punishment, a quasi-criminal sanction for which Defendants have not been afforded the specific procedural safeguards prescribed in the New York Constitution as well as the Fifth and Sixth Amendments to the United States Constitution, and would violate constitutional proscriptions against excessive fines.

TWENTY-SECOND AFFIRMATIVE DEFENSE

With respect to Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of <u>BMW of North</u>

America v. Gore, 517 U.S. 559 (1996); Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001); State Farm Mutual Auto Ins. Co. v. Campbell, 538 U.S. 408 (2003); and Philip Morris USA v. Williams, 549 U.S. ____, 127 S. Ct. 1057 (2007), together with all such standards applicable under New York law.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the First Amendment of the Constitution of the United States and Article I, Section 8 of the Constitution of the State of New York.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Any recovery by Plaintiff must be reduced or offset by amounts Plaintiff has received or will receive from others for the same injuries and damages alleged by Plaintiff in the Complaint pursuant to Section 15-108 of the General Obligation Law.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred in whole or in part by the applicable statutes of limitations or repose, or by operation of laches.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred in whole or in part by the doctrines of waiver and equitable estoppel.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Any damages allegedly recoverable by Plaintiff should be reduced in accordance with Rule 4545 of the New York Civil Practice Law and Rules.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because Defendants did not owe any legal duty to Plaintiff or, if Defendants did owe such a legal duty, Defendants did not breach that duty.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by her abuse and/or misuse of the Ortho Evra® product.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiff has failed to plead fraud and/or misrepresentation with the particularity requirements under Rule 9(b) of the Federal Rules of Civil Procedure.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff cannot recover under their consumer protection claims because Defendants were not engaged in consumer oriented conduct as required by the New York consumer protection laws.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's consumer protection claims are preempted by New York law, including N.Y. Gen. Bus. Law § 399.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Defendants specifically deny each and every allegation contained in the Complaint by which liability is sought to be imposed upon them, and give notice that they intend to rely upon such other defenses as may become available or appear during discovery in this case and hereby reserve the right to amend this Answer to assert any such defenses.

WHEREFORE, having fully answered, Defendants request that Plaintiff's Complaint against them be dismissed at Plaintiff's cost and that this Court grant any further relief which it deems just and equitable.

JURY DEMAND

Defendants hereby demand a trial by jury of all the facts and issues so triable pursuant to 38(b) of the Federal Rules of Civil Procedure.

Respectfully submitted,

Dated: June 27, 2007

/s/ Patrick G. Broderick
Robert W. Sparks (RS 4250)
Debra D. O'Gorman (DO 1643)
Patrick G. Broderick (PB 7282)
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Attorneys for Defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research and Development, L.L.C., Alza Corporation, and Ortho-McNeil Pharmaceutical, Inc.

CERTIFICATE OF SERVICE

Patrick G. Broderick, an attorney admitted to practice before this Court, hereby affirms under penalty of perjury that on June 27, 2007, I caused a true and correct copy of the foregoing Defendants' Answer, Affirmative Defenses And Jury Demand to be served via electronic case filing upon all parties so registered, and via overnight delivery upon:

Elliot L. Lewis, Esq.
LAW OFFICE OF JOSEPH M.
LICHTENSTEIN, P.C.
170 Old Country Road, Suite 301
Mineola, New York 11501

ATTORNEYS FOR PLAINTIFF

Dated: New York, NY June 27, 2007

/s/ Patrick G. Broderick
Patrick G. Broderick (PB 9556)